

Roxil®

Cefadroxil Capsule and Oral Suspension

Composition:

Roxil 500: Each capsule contains Cefadroxil equivalent to Cefadroxil anhydrous 500 mg.

Excipients: Microcrystalline cellulose, crospovidone, starch, sodium lauryl sulfate, silicon dioxide and magnesium stearate.

Roxil Oral Suspension: Each 5 ml of reconstituted suspension contains Cefadroxil equivalent to Cefadroxil anhydrous 250 mg.

Excipients: Sucrose, monobasic sodium phosphate, sodium bicarbonate, saccharin sodium, sodium benzoate, xanthan gum, talc, E124 and flavours.

Properties:

Roxil is a trade name of anti-bacterial drug, Cefadroxil, which is an orally active cephalosporin. Roxil is rapidly absorbed after oral administration and has longer duration of action than other cephalosporins. Over 90 % of the doses are excreted unchanged in the urine within 24 hours.

The main susceptible microorganism are:

- Beta-hemolytic streptococci.
- Staphylococci, including a penicillinase-producing strains.
- Streptococcus (Diplococcus) pneumoniae.
- Escherichia coli.
- Proteus mirabilis.
- Klebsiella species.
- Moraxella (Branhamella) catarrhalis.

Cefadroxil has poor activity against Haemophilus influenza and it is not active against most strains of Enterobacter species.

Indications:

Roxil is indicated for the treatment of patients with infection caused by susceptible strains of the designated organism in the following diseases:

- Urinary tract infection caused by E. Coli, P. mirabilis, and Klebsiella species.
- Skin and skin structure infections caused by staphylococci and/or streptococci.
- Pharyngitis and tonsillitis caused by Group A beta-hemolytic streptococci.

Note: Culture and susceptibility tests should be initiated prior to and during therapy. Renal functions studies should be performed when indicated.

Contraindications:

Roxil is contraindicated in patients with known allergy to the cephalosporins or to any of its component.

Precautions:

In adult patients with renal impairment, the initial dose of Roxil is 1000 mg and the maintenance dose is 500 mg at the time intervals listed below:

Creatinine Clearance	Dosage Intervals
0 - 10 ml / min	36 hours
10 - 25 ml / min	24 hours
25 - 50 ml / min	12 hours

- Roxil should be prescribed with caution in individuals with history of gastrointestinal disease particularly colitis.

- A positive direct Coomb's tests of new borns whose mothers have received cephalosporin before parturition may be due to the drug.

Interaction with other drugs:

Probencid increases the serum level of Cefadroxil by blocking its renal excretion. Furosemide and aminoglycoside antibiotics are additive nephrotoxicity of Cefadroxil.

Warnings:

Before therapy with Roxil is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions. About 10 % of penicillin sensitive patients will also be allergic to the cephalosporins. If an allergic reaction to Roxil occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine

and other emergency measures.

There are no adequate and well controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed.

Caution should be exercised when Cefadroxil is administered to a nursing mother.

Dosage and Administration:

Adults : 500 mg to 1 g twice daily.

Children: Under 1 year : 25 mg / kg daily in divided doses.

1 to 6 years : 250 mg twice daily.

Over 6 years : 500 mg twice daily.

Overdosage:

After gastric emptying no action is required other than general support and observation.

Side Effects:

Gastrointestinal: Pseudomembranous colitis symptoms, diarrhea and nausea may occur during or after antibiotic treatment.

Others: Rash, urticaria, pruritus, vaginitis, neutropenia, minor elevations in serum transaminase and Stevens-Johnson syndrome have been rarely observed.

Consult your pharmacist or physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15 - 30 °C).

Shake well reconstituted suspension before use.

Do not use beyond the expiry date or if the product shows any sign of deterioration.

Presentations:

Roxil 500 : Pack of 20 Capsules.

Roxil Oral Suspension: Bottle of 100 ml when reconstituted.

Hospital packs are available.

Reconstitution of Oral Suspension:

Add water up to the line marked on the bottle. Shake well then readjust the volume with water.

The reconstituted suspension can be used within 14 days if kept in refrigerator or 7 days if kept at room temperature.

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



Manufactured by:

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